<u>REMARKS</u>

This paper is in response to the Final Official Action mailed April 2, 2008. In the present paper, no amendments are made. Claims 1-7, 9-19, 21-31 and 33 are now presented for the Examiner's consideration in view of the following remarks.

The Invention

The inventors have discovered a system and method for identifying and communicating with potential clinical trial participants. The invention addresses two long-standing interrelated problems. First, the problem of data anonymity has, in the past, restricted systems for identifying potential clinical trial participants to systems that work on a small, localized scale (present specification at [0004]-[0005]). Second, there is a need to reliably identify a large pool of potential clinical trial participants from which to choose, due to the often narrow participant selection criteria of a given trial, and the high cost of replacing an incorrectly selected participant (present specification at [0003]-[0004]).

The inventors have solved the problem of data anonymity by replacing the identities of patients in a database with secure patient codes. To the inventors' knowledge, that advance is unique in the field of clinical trial candidate selection. The inventors have furthermore utilized a database containing transactions between health care providers and payers to identify clinical trial candidates. Using such a database has significant advantages in candidate pool size and data quality. To the inventors' knowledge, however, such a database had never been utilized to identify clinical trial candidates, at least in part because of patient anonymity concerns. The present invention solves both longstanding problems.

In the Final Official Action, the Examiner has repeated the rejections of the previous Official Action, and has responded to the arguments accompanying Applicants' amendment. Applicants respectfully assert that the combinations made by the Examiner in rejecting each of the claims are improper for the following reasons:

Combining Knight and Thomas

Applicants respectfully submit that the Examiner is incorrect in making the combination of Knight and Thomas in the rejection. Knight was cited as teaching a method for identifying clinical trial candidates. Knight starts with a pool of candidates that has applied to participate in clinical trials using an HTML form (Knight at [0057]). Knight matches those candidates with clinical trials under the protection of an environment created by layered firewalls (Knight at [0101] - [0105]; FIG. 29).

The Examiner admits that Knight does not teach replacing, determining and forwarding patient identities to allow anonymity. To cure that deficiency, the Examiner combines Knight with Thomas, which is directed to a tool for anonymizing medical data. Thomas addresses the problem of grouping medical images of a single patient that are obtained over time:

> One known flaw with present anonymizing procedures stems from the fact that individual diagnostic results or medical images are anonymized independently. The result of this methodology can result in diagnostic results and/or images from an individual patient's secondary or follow-up visits being assigned a unique anonymous header. As patient follow-up or continued care proceeds, the information sent to research facilities cannot therefore be traced or tracked as coming from a single patient. This can hamper the research facilities ability to monitor both an

individual's medical progression as well as its ability to accurately

access a statistical sample as the precise number of individual's

submitted may be unknown. In addition to hampering research

facilities, these procedures can also hamper advancements in

patient care. Discoveries or analysis derived at the research level

in regards to a specific or group of patient results cannot be

retraced by the hospital or primary caregiver in order to apply

these results or insights to a specific patient or group of patients.

In this fashion, present anonymizing methodologies can hamper a

physician's ability to utilize research and development results or

discoveries for specific patients.

To solve that problem, when a new medical image arrives, Thomas searches a database of patient

identifiers, and a new anonymous identifier is assigned only if the patient has never before been

processed (Thomas at [0015]). That avoids assigning multiple identifiers to a single patient.

Thomas further teaches that the single patient identifier is helpful in tracing the data back to a

specific patient to allow for improved patient care (Thomas at [0017]).

In the Final Official Action, the Examiner has alleged that one of ordinary skill in the art

would be motivated to combine Knight and Thomas "for anonymizing medical data with

improved patient file continuity and to share data between hospitals and research and design

facilities both internal and external to the hospital while protecting patient confidentiality" (FOA

at 3, lines 9-14). As to improving patient file continuity, Applicants assert that the phrase

"patient file continuity" in Thomas (at [0006]) refers to the ability to group data as coming from

a single patient. That problem is particular to a system such as that described in Thomas wherein

images from a single patient arrive separately, spaced apart in time. In contrast, data in Knight is

taken from one of more HTML forms filled out by a candidate. It is already clear in Knight

which data should be grouped together with a single patient - there is no problem of "patient file

continuity." Applicant therefore asserts that "improving patient file continuity" is not a reason to combine Knight and Thomas.

Quoting Thomas in the Final Official Action, the Examiner urges that another motivation to combine Knight and Thomas is "to share data between hospitals and research and design facilities both internal and external to the hospital while protecting patient confidentiality." One in possession of the Knight reference, however, would not look to Thomas for a scheme to "share data between hospitals and research and design facilities" because the data used by Knight in identifying clinical trial candidates is internal. Neither Knight nor Thomas teaches or suggests the use of outside data for identifying clinical trial candidates.

Further, the passage of Thomas referred to by the Examiner discusses the need to freely share detailed medical data such as medical diagnostic output and images in the research community (Thomas at [0002]). In sharp contrast, the data processed by the Knight system is from HTML forms completed by the patient or patient's physician for the express purpose of applying for participation in clinical trials. Unlike the "medical diagnostic output and images" of Thomas, the patient-generated forms of Knight would be of little or no value to the research community. The use to which Knight puts data from those forms is to identify clinical trial candidates. That function is performed within a firewalled environment. There is no motivation to "freely share" that data and there is no motivation to add Thomas' data anonymizing techniques to Knight's clinical trial recruitment system.

In sum, Applicants therefore assert that there is no reason to combine Knight and Thomas, because (1) there is no "data continuity problem," (2) the data of Knight is internal and is not of the type that would be shared by a research community, and (3) the Knight system

maintains the data within a firewalled environment and has no need for additional patient

confidentiality protection.

Combining Saeed with the combination of Knight and Thomas

To identify clinical trial candidates, the system of Knight relies exclusively on

dynamically generated HTML questionnaire forms that are filled out by potential applicants.

Knight's pool of potential candidates is therefore limited to a group of candidates that is actively

seeking participation in a trial. Knight in no way addresses or even suggests one of the major

problems solved by the present invention: finding candidates in the first place (present

specification at [0004] - [0005]). Instead, the Knight system presupposes that potential

candidates will come to the system, and Knight simply addresses how to match those candidates

with clinical trials.

Thomas, which in no way contemplates the identification of clinical trial candidates,

certainly does not suggest the use of any outside database for that purpose.

To cure that deficiency, the Examiner has combined the Knight and Thomas references

with Saeed, which is alleged by the Examiner to teach receiving clinical data records from an

entity controlling a database containing transactions between health care providers and payers

(FOA at 13, lines 10-13). The Examiner states:

> It would have been obvious to combine Saeed et al. with the other
> references since the information from this database could be used
> to **track** candidates for clinical trials (see column 9, lines 27-29 of
> Saeed et al.)

FOA at 13, lines 14-16 (*emphasis in original*). Applicants assert that there is no motivation in

any of the three references to use information from a database like the Saeed database to track

candidates for clinical trials. Knight explicitly teaches the use of an internal database created

expressly for the purpose of recruiting clinical trial candidates. Neither Thomas nor Saeed are

concerned with clinical trials in any way.

The citation of Saeed provided by the Examiner discusses the use of a claims history

database:

> The claims history database 62 includes the administrative data
> transactions that are used for audits and information tracking.

Saeed at col. 9, lines 27-29. Saeed provides absolutely no suggestion to forward data from the

claims history database to a clinical trial candidate identification service. The "track" function of

Saeed referred to by the Examiner is instead performed by a tracking module 58 that is *internal*

to the medical service provider system 28:

> Still referring to FIG. 8, the medical service provider
> system 28 includes an administrative data transaction tracking
> module 58 in communication with the network interface 48 for
> tracking the generated administrative data and the processed
> administrative data provided by the selected practice management
> agent system 38 for reporting and auditing purposes. The
> transaction tracking module 58 collects and stores, in a medical
> service provider storage area 60, all the administrative data on a
> transaction by transaction basis for future audits and information
> tracking. *The transaction tracking module 58 is designed to*
> *monitor and track the internal use of the medical service provider*
> *system 28* and is supplemental to an audit trail created by the
> coordinator system 24. The tracked administrative data is stored in
> a claims history database 62 in the data storage 60 of the medical
> service provider system 28.

Saeed at col. 8, lines 38-53 (*emphasis added*). Applicants respectfully submit that the "tracking"

function of Saeed therefore provides absolutely no motivation to combine the clinical trial

recruiting system of Knight with a receipt of clinical data records alleged to be taught by Saeed.

Conclusion

Applicants therefore respectfully assert that claims 1-7, 9-19, 21-31 and 33 and are in

condition for allowance, and earnestly request that the Examiner issue a Notice of Allowance.

Should the Examiner have any questions regarding the present case, the Examiner should

not hesitate in contacting the undersigned at the number provided below.

Respectfully,

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